

Appl. No. : 09/447,227
Filed : November 22, 1999

PROPOSED AMENDMENTS TO THE CLAIMS

1-20. (Cancelled)

21. (Currently amended) A method of monitoring glucose levels, comprising:

a) providing i) a host, and ii) a device comprising a housing, a sensing membrane, a first domain, a second domain, and means for determining the amount of glucose in a biological fluid; wherein said device comprising a first domain is positioned more distal to said device, housing than said second domain; wherein said first domain supports tissue ingrowth and ~~interferes with barrier cell layer formation, a~~ ; wherein said sensing membrane is positioned more proximal to said device, housing than said second domain; wherein said sensing membrane ~~comprising~~ comprises an enzyme, ~~and a~~ ; wherein said second domain is situated between said first domain and said sensing membrane; and wherein said second domain ~~is resistant to cellular attachment and~~ is impermeable to inflammatory cells and cell processes; and

b) implanting said device in said host under conditions such that said device measures said glucose accurately for a period of time exceeding 90 days, wherein said device is anchored in said host by tissue ingrowth.

22. (Original) The method of claim 21, wherein said device measures said glucose accurately for a period exceeding 150 days.

23. (Cancelled)

24. (Original) The method of claim 21, wherein said implanting is subcutaneous.

25-27. (Cancelled)

28. (Currently amended) A method of measuring glucose in a biological fluid, comprising the steps of:

providing i) a host, and ii) an implantable device comprising a sensor capable of continuous glucose sensing, said implantable device comprising a housing, a sensing membrane, a first domain, and a second domain; wherein said a first domain is positioned more distal to said implantable device, housing than said second domain; wherein said first domain supports tissue ingrowth and ~~interferes with barrier cell layer formation, a~~ ; wherein said sensing membrane is positioned more proximal to said implantable device, housing than said second domain; wherein said sensing membrane ~~comprising~~ comprises an enzyme, ~~and a~~ ; wherein said second domain is situated between said first domain and said sensing membrane; and wherein said second domain

Appl. No. : 09/447,227
Filed : November 22, 1999

is ~~resistant to cellular attachment and~~ is impermeable to inflammatory cells and cell processes;
and

implanting said device subcutaneously, wherein said device is anchored in said host by tissue ingrowth.

29. (Previously added) A method of measuring glucose according to claim 28, further comprising the step of calibrating the implantable device subsequent to implanting said implantable device.

30. (Currently amended) A method of measuring glucose in biological fluid, comprising the steps of:

providing i) a host, and ii) an implantable device comprising a sensor capable of continuous glucose sensing, said implantable device comprising a housing, a sensing membrane, a first domain, and a second domain; wherein said first domain is positioned more distal to said implantable device, housing than said second domain; wherein said first domain supports tissue ingrowth and interferes with barrier cell layer formation, a; wherein said sensing membrane is positioned more proximal to said implantable device, housing than said second domain; wherein said sensing membrane comprising comprises an enzyme, and a; wherein said second domain is situated between said first domain and said sensing membrane; and wherein said second domain is resistant to cellular attachment and is impermeable to inflammatory cells and cell processes;

implanting said device subcutaneously in said host, wherein said device is anchored in said host by tissue ingrowth; and

transmitting data from said implantable device to an external device.

31. (Currently amended) A method of measuring glucose in a biological fluid, comprising the steps of: providing i) a host, and ii) an implantable device comprising a sensor capable of continuous glucose sensing, said implantable device comprising a housing, a sensing membrane, a first domain, and a second domain; wherein said first domain is positioned more distal to said implantable device, housing than said second domain; wherein said first domain supports tissue ingrowth and interferes with barrier cell layer formation, a; wherein said sensing membrane is positioned more proximal to said implantable device, housing than said second domain; wherein said sensing membrane comprising comprises an enzyme, and a; wherein said second domain is situated between said first domain and said sensing membrane; and wherein

Appl. No. : 09/447,227
Filed : November 22, 1999

said second domain is ~~resistant to cellular attachment and~~ is impermeable to inflammatory cells and cell processes;

implanting said device wholly subcutaneously in said host, wherein said device is anchored in said host by tissue ingrowth;

and transmitting data by telemetry from said wholly implantable device to an external device.

32. (Currently amended) A method of measuring glucose in a biological fluid, comprising the steps of:

- a) providing a host;
- b) providing an implantable device comprising a sensor capable of continuous glucose sensing, said sensor having an interface tip, said implantable device comprising a housing, a sensing membrane, a first domain, and a second domain; wherein said first domain is positioned more distal to said implantable device, housing than said second domain; wherein said first domain supports tissue ingrowth and interferes with barrier cell layer formation; a; wherein said sensing membrane is positioned more proximal to said implantable device, housing than said second domain; wherein said sensing membrane comprising an enzyme, and a; wherein said second domain is situated between said first domain and said sensing membrane; and wherein said second domain is resistant to cellular attachment and is impermeable to inflammatory cells and cell processes;
- c) implanting said device subcutaneously into tissue of said host so as to elicit a foreign body capsule as a result of the response of said host to the introduction of said implantable device, said sensor interface tip communicating with the tissue of said host such that said tip is anchored by tissue ingrowth in said foreign body capsule.

33. (Previously added) A method according to claim 32, wherein said device is wholly implanted subcutaneously in said host.

34. (Previously amended) A method according to claim 32, wherein said sensor tip is anchored in said foreign body capsule by the provision of a capsular attachment layer on said sensor.

35. (Previously amended) A method according to claim 34, wherein said sensor tip is further anchored by the provision of an angiogenic layer on said sensor.

Appl. No. : 09/447,227
Filed : November 22, 1999

36. (Previously added) A method according to claim 34, wherein said capsular attachment layer is non-smooth.

37. (Previously added) A method according to claim 36, wherein said non-smooth layer includes surgical grade polyester velour.

38. (Currently amended) A method of monitoring glucose levels, comprising:

a) providing i) a host, and ii) a device comprising a housing and a sensor capable of continuous glucose sensing, said sensor ~~including~~ comprising a sensing membrane, a first domain, a second domain, and a vascularization promotion layer, said device comprising a; wherein said first domain is positioned more distal to said device, housing than said second domain; wherein said first domain supports tissue ingrowth and interferes with barrier cell layer formation, a; wherein said sensing membrane is positioned more proximal to said device, housing than said second domain; wherein said sensing membrane comprising an enzyme, and a; wherein said second domain is situated between said first domain and said sensing membrane; ~~and wherein said second domain is resistant to cellular attachment and is impermeable to inflammatory cells and cell processes; and~~

b) wholly implanting said device subcutaneously in said host under conditions such that said device provides continuous glucose sensing, wherein said device is anchored in said host by tissue ingrowth.

39. (Previously added) A method according to claim 38, wherein said vascularization promotion layer is an angiogenic layer.

40. (Previously added) A method according to claim 38, wherein said sensor further includes a capsular attachment layer.

41. (Previously added) A method according to claim 38, wherein said implant is sized and configured for being wholly implanted subcutaneously.

42. (Previously added) A method according to claim 41, further including the step of transmitting data from said wholly implanted device telemetrically.

43. (Previously added) The method of claim 21, wherein said device measures said glucose accurately for a period exceeding 360 days.

44. (Previously added) The method of claim 21, wherein said enzyme comprises glucose oxidase.

Appl. No. : 09/447,227
Filed : November 22, 1999

45. (Previously added) The method of claim 28, wherein said enzyme comprises glucose oxidase.
46. (Previously added) The method of claim 30, wherein said enzyme comprises glucose oxidase.
47. (Previously added) The method of claim 31, wherein said enzyme comprises glucose oxidase.
48. (Previously added) The method of claim 32, wherein said enzyme comprises glucose oxidase.
49. (Previously added) The method of claim 38, wherein said enzyme comprises glucose oxidase.
50. (Previously added) The method of claim 21, wherein said device further comprises an electrolyte phase, wherein said electrolyte phase is situated between said sensing membrane and said sensor.
51. (Previously added) The method of claim 28, wherein said device further comprises an electrolyte phase, wherein said electrolyte phase is situated between said sensing membrane and said sensor.
52. (Previously added) The method of claim 30, wherein said implantable device further comprises an electrolyte phase, wherein said electrolyte phase is situated between said sensing membrane and said sensor.
53. (Previously added) The method of claim 31, wherein said implantable device further comprises an electrolyte phase, wherein said electrolyte phase is situated between said sensing membrane and said sensor.
54. (Previously added) The method of claim 32, wherein said implantable device further comprises an electrolyte phase, wherein said electrolyte phase is situated between said sensing membrane and said sensor.
55. (Previously added) The method of claim 38, wherein said device further comprises an electrolyte phase, wherein said electrolyte phase is situated between said sensing membrane and said sensor.